



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/527,830

10/20/2005

Toshimitsu Nakashima

21581-00476-US

4578

30678

7590

07/07/2010

CONNOLLY BOVE LODGE & HUTZ LLP

1875 EYE STREET, N.W.

SUITE 1100

WASHINGTON, DC 20006

EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

07/07/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,830	Applicant(s) NAKASHIMA ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/10, 5/10</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 7, 8, and 15 have been cancelled. Claims 1-6 and 9-14 are still at issue and are present for examination.

Applicants' arguments filed on 4/2/10, have been fully considered and but are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 2 and 9-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 1/11/08.

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

claim 1 (upon which claims 3-6 depend) is confusing in the recitation of "substantially consists of" as it is unclear if this is open language, closed language or intended to be synonymous with "consisting essentially of".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1652

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Satoshi et al. (JP 2001/340078) in view of Naylor et al. (WO 96/25509). The rejection is explained in the previous Office Action.

Applicants argue that while Satoshi et al. teach methods of controlling the molar ratio of 3HH in a 3HB-co-3HH copolyester, the method suggested therein requires altering the composition of the carbon source and at least two carbon sources and employs a fatty acid. First it should be noted that what applicants are trying to say here is completely unclear. Satoshi clearly teaches that using a single natural oil or fat as carbon source was known in the art and further teaches using mixtures of natural fats and oils as carbon source as well as mixtures of one or more fats or oils and a fatty acid. However, it is not

clear how this distinguishes from what is claimed in the instant application. Clearly use of a single natural oil or fat or a mixture of two or more natural oils or fats is encompassed within the scope of the instant claims. To the extent that applicants are arguing that Satoshi et al. teaches that one can alter the ratio of 3HH by adding a fatty acid to the natural oils and fats, it is noted that Satoshi et al. does not require this addition, it is merely one embodiment taught (and the other disclosed embodiment of a mixture of two or more natural oils is clearly encompassed within applicants claims).

Applicants argue that Naylor et al. refer to an average oil uptake ratio but require a fatty acid such as propionic acid be added in order to produce a copolyester. However, this is not persuasive because the rejection did not suggest using the carbon sources taught by Naylor et al. but instead suggested using Naylor et al.'s carbon source feeding strategy in the method of Satoshi et al. which clearly includes using carbon sources such as recited in the instant claims. One would have been motivated to do so as Naylor et al. teach their feeding strategy as a means to avoid accumulating a toxic concentration of substrate and Satoshi et al. teach that fatty acids produced from metabolism of the oils and fats used as the carbon source may be cytotoxic at high levels.

Applicants argue that the purpose of Naylor et al. was to avoid toxicity. Average oil uptake ratio in Naylor et al. has nothing to do with controlling the monomer ratio of the copolyester. However, this is not persuasive as it is not necessary for a finding of obviousness that the modification of the prior art be made for the same reasons as applicants reasons. All that is necessary is that the art provide a reason to make the necessary modification to arrive at the claimed methods not that the reason be identical to that of applicants. (see MPEP 2144). The avoidance of toxicity clearly provides a skilled artisan the needed reason to make the necessary modification particularly in view of the teaching of Satoshi et al. that such toxicity is a potential problem within the methods taught by Satoshi et al. as well.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

Art Unit: 1652

is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652